UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ASSOCIATION FOR MOLECULAR PATHOLOGY, *ET AL.*,	)	
Plaintiffs,	)	
v.	)	09 Civ. 4515 (RWS)
UNITED STATES PATENT AND TRADEMARK OFFICE, *ET AL.*,	)	ECF
Defendants.	)	

BOSTON PATENT LAW ASSOCIATION'S *AMICUS* BRIEF SUPPORTING THE MYRIAD DEFENDANTS' OPPOSITION TO SUMMARY JUDGMENT, THEIR CROSS-MOTION FOR SUMMARY JUDGMENT, AND THE USPTO'S MOTION FOR JUDGMENT ON THE PLEADINGS

Of Counsel:
Erik Paul Belt
Co-Chair, BPLA *Amicus* Committee
Maria Laccotripe Zacharakis, Ph.D.
McCARTER & ENGLISH, LLP
265 Franklin Street
Boston, MA 02110
Tel.: (617) 449-6500
Fax: (617) 607-9200

Lee Carl Bromberg
Lori J. Shyavitz
McCARTER & ENGLISH, LLP
265 Franklin Street
Boston, MA 02110
Tel.: (617) 449-6500
Fax: (617) 607-9200

Attorneys for Amicus Curiae, Boston Patent Law Association

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s):

CASES

CONSTITUTIONAL AUTHORITY AND STATUTES

OTHER AUTHORITIES

F. Scott. Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science--A Response to Rai and Eisenberg,* 95 Nw. U. L. Rev. 691 (2001) ..... *passim*

Edmund W. Kitch, *The Nature and Function of the Patent System,* 20 J.L. & Econ. 265, (1977) 7

Yusing Ko, *An Economic Analysis of Biotechnology Patent Protection,* 102 Yale L.J. 777 (1992) 6, 9

Benjamin Lewin, *Genes V* (1994) 20, 21, 24

Ronald J. Mann, *The Role of Patents in Venture-Backed Software Start-Ups*, Acad Advisory Council Bulletin (2007), *available at* www.pff.org/issues-pubs/ip/bulletins/bulletin2.1softwareventurepatents.pdf 6

Erik S. Maurer, *Note, An Economic Justification for a Broad Interpretation of Patentable Subject Matter,* 95 Nw. U. L. Rev. 1057 (2001) 9, 14

Giles S. Rich, *The Principles of Patentability*, 42 J. Pat. Off. Soc'y 75 (1960) 7

Giles S. Rich, *The Relation between Patent Practices and the Anti-Monopoly Laws*, 24 J. Pat. Off. Soc'y 159 (1942) 6, 9

David Silverstein, *Patents, Science and Innovation: Historical Linkages and Implications for Global Technological Competitiveness,* 17 Rutgers Computer & Tech. L.J. 261 (1991) 3, 13

Tufts Center for the Study of Drug Development, Press Release: *Average Cost to Develop a New Biotechnology Product is $1.2 Billion* (November 9, 2006), *available at* http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=690 4

U.S. Patent No. 141,072, *available at* http://www.google.com/patents 18

U.S. Patent No. 730,176, *available at* http://www.google.com/patents 18

John P. Walsh *et al.*, *Patents, Material Transfers and Access to Research Inputs in Biomedical Research*, Final Report to the National Academy of Sciences' Committee on Intellectual Property Rights in Genomic and Protein-Related Inventions, 37 (2005), *available at* www2.druid.dk/conferences/viewpaper.php?id=776&cf=8 11

James D. Watson *et al.*, *Recombinant DNA* (2d ed. 1992) ..... *passim*

World Health Organization, *Fact Sheet No. 297: Cancer* (2006), *available at* http://www.who.int/mediacentre/factsheets/fs297/en/index.html 23

THE BOSTON PATENT LAW ASSOCIATION'S INTEREST

The Boston Patent Law Association ("BPLA") is a nonprofit association, approximately 900 members strong, of attorneys and other intellectual property professionals. The BPLA sponsors educational programs and forums concerning patent, trademark, and other intellectual property rights. The BPLA's members serve a broad range of clients who rely on the patent system: independent inventors, corporations, investors, and non-profit and academic institutions, such as universities and research hospitals. These clients operate in an equally broad range of industries, including life sciences, high-tech, consumer goods, and traditional manufacturing.

The BPLA desires a robust patent system that fulfills its constitutional role of promoting the "Progress of Science and the useful Arts." U.S. Const., art. I, § 8, cl. 8. A decision in this case limiting the scope of patent protection will quash incentives for innovation, to the detriment of the American economy and the public health and welfare. Without the incentives of the patent system, the introduction and commercial availability of new and better treatments and diagnostics for cancer and other diseases will decline. Accordingly, the BPLA respectfully urges this Court to reject Plaintiffs' attempt to stifle innovation in the biotechnology field.[1]

SUMMARY OF ARGUMENT

The Constitutional role of patents is "[t]o promote the Progress of Science and the useful Arts." U.S. Constitution, Art. I, § 8, cl. 8. Patents fulfill this Constitutional role and are vital to the American economy. Far from stifling innovation or competition, as Plaintiffs contend, patents actually promote innovation, competition, and wider availability of new technologies.

---

[1] This brief is solely the work of the BPLA and reflects its consensus view. The stated arguments and positions do not necessarily reflect the views of any individual BPLA member, associated firm, or client of a member. No party in this case or any other person or organization authored this brief in whole or in part or contributed any money to fund its preparation or submission. All legal work to prepare and submit this brief was contributed *pro bono* by the BPLA's counsel in this matter, McCarter & English LLP.

As seen in Part I , patents promote innovation in a number of ways, including through (a) encouraging investments in innovation, (b) spurring creativity, and (c) facilitating the exchange of information. The benefits of the patent system are particularly evident in the life sciences field, in which the cost to develop, test, and commercialize a new biotechnology product ranges in the hundreds of millions of dollars. Patents are needed to attract and protect such investments.

Historical and economic analysis show a significant link between a healthy patent system and a healthy economy. Public distrust of patents leads to periods of economic and technological decline. Plaintiffs advocate a similar distrust. But Plaintiffs ignore the big picture. Without the incentives of patents, many life-saving products, including Myriad's *BRCA1* and *BRCA2* tests, would not be available to *anyone*--let alone to the individual plaintiffs--because companies would not risk the investment needed to develop and bring them to market. Given the importance of patents to the economy and public welfare, the subject matter eligible for patent protection under 35 U.S.C. § 101 should be entitled to as broad a scope as possible.

As argued in Part II, Myriad's patents are directed to patentable subject matter. These patents do not claim mere products of nature. Rather, they are directed to new compositions that did not exist in nature and that possess qualities and properties distinct from those of the corresponding naturally-occurring genes. Unlike the naturally-occurring versions, the isolated DNA products of Myriad's patents can be used in diagnostics and therapies that greatly benefit society by helping numerous women to detect predispositions to breast or ovarian cancer. In short, Myriad has patented new and practical applications for genes, not the genes themselves. For similar reasons, and as seen in Part III, Myriad's patents are not unconstitutional. The Constitution delegated to Congress the task of defining patent eligibility, and Congress decided that "any new and useful" product or process or improvement thereof is patent-eligible.

ARGUMENT

I. PATENTS PROMOTE INNOVATION AND BENEFIT SOCIETY

More than any other factor, technological innovation drives the American economy and enhances its productivity and competitiveness, "thereby strengthening and enriching the nation." *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.,* 62 F.3d 1512, 1529 (Fed. Cir. 1995) (Newman, C.J. concurring) (citations omitted), *rev'd,* 520 U.S. 17 (1997). Innovation, in turn, depends significantly on patents. David Silverstein, *Patents, Science and Innovation: Historical Linkages and Implications for Global Technological Competitiveness*, 17 Rutgers Computer & Tech. L.J. 261, 263 (1991) ("Historically, the U.S. patent system has played a significant role in both stimulating innovation and promoting the commercialization of new technologies").

Patents promote the "Progress of Science and the useful Arts" in several ways. For example, companies and individuals will not invest in developing a new technology unless they can be assured of some measure of market exclusivity. Patent law, of course, provides the "exclusive Right" to practice the patented invention for "limited Times" and thus fosters investment in innovation. *See* U.S. Const., art. I, § 8, cl. 8; *see also* 35 U.S.C. 154(a) (a patent grants "the right to exclude others from making, using, offering for sale, or selling the inventions throughout the United States" during the limited term of the patent). Without such protection, investments in innovation are subject to the "free-rider" problem in which copyists can take advantage of the pioneering work of others. Free riding, in turn, stifles innovation by frustrating the exchange of information and by devaluing incentives for innovation. Abraham Lincoln himself recognized this free-rider problem and how exclusive patent rights fuel innovation:

> These [patent rights] began in England in 1624; and, in this country, with the adoption of our constitution. Before then, any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited

> time, the exclusive use of his inventions; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.

As quoted in Mark Blaxill & Ralph Eckardt, *The Invisible Edge: Taking Your Strategy to the Next Level Using Intellectual Property* 41 (2009). As discussed below, patents promote innovation and, contrary to Plaintiffs' assertions, do not stifle research or competition.

A. Biotechnology Inventions Are Costly to Develop; Patents Protect Investment in such Inventions

Biotechnology inventions are costly to develop. A Tufts University study estimates that the cost of discovering, developing, and then bringing to market a new biotechnology product averages $1.2 billion. *See* Tufts Center for the Study of Drug Development, Press Release: *Average Cost to Develop a New Biotechnology Product is $1.2 Billion* (November 9, 2006), *available at* http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=690. Another study, conducted by researchers from the Federal Trade Commission's Bureau of Economics, calculates that development costs range from about $500 million to as much as $2 billion. *See* Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is it Really $802 Million?*, 25 Health Affairs 420 (March/April 2006).[2]

Adding to this cost is the time involved in product development. The time from the start of clinical trials to FDA approval averages 90.3 months (7.5 years). Joseph D. DiMasi *et al.*, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 164-165 (2003). The time from initial drug discovery to the start of human testing averages 52 months (4.33 years). *Id.* at 166. Thus, getting a new product to market can take twelve years or

---

[2] *See also* Joseph D. DiMasi *et al.*, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 166 (2003) (estimating the cost at $802 million). The dollar figures reported above reflect "capitalized" costs, which factor in the time value of money, the cost of capital, and other accounting factors. The actual out-of pocket costs are lower but still significant. For example, according to the Tufts study cited above, out-of-pocket costs for pre-clinical product development averages $198 million and $361 million for clinical trials.

more. *See also* Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int'l Econ. L. 849, 851 (2002) (drugs take "several hundred million dollars to discover, develop, and gain regulatory approval," and the process can "take more than a decade to complete").

Another factor adding to these costs is the risk of failure. Most product candidates never make it to market. Either they fail to make it out of the lab, to emerge from clinical trials, or to gain FDA approval. According to the Tufts study cited above, the clinical success rate for biotechnology products is only about 30%--meaning that only one in three candidates that begins clinical trials ever emerges with FDA approval. The success rate for conventional drugs is even less. *See* Grabowski, *Patents, Innovation*, *supra* at 851 ("Typically, fewer than 1% of the compounds examined in the pre-clinical period make it into human testing. Only 22% of the compounds entering clinical trials survive the development process and gain FDA approval").

Given these high costs, time lags, and risks, it is no wonder that patents have become so important to the biotech and pharmaceutical industries. Companies and investors are wary of funding new technologies absent strong patent protection. Patents assure the market exclusivity that will protect these high risk investments. *See Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir.) ("encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude"), *modified*, 771 F.2d 480 (Fed. Cir. 1985).

Accordingly, a patent is the biotech community's *sine qua non* for funding research and commercializing new products. *See* Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 Rutgers Computer & Tech. L. J. 1, 22 (1991) ("one concrete fact is clear: patents are critical to the growth and competitiveness of American biotechnology because patents are something that investors expect"); F. Scott. Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science--A Response to Rai*

and Eisenberg, 95 Nw. U. L. Rev. 691, 704 (2001) ("The ability for patents to bring immense amounts of, and diversity in, sources of funding and other resources to the basic biological research community is recognized as a critical factor in the great success the community has enjoyed since 1980"); Grabowski, *Patents, Innovation, supra* at 851-52 (patents are essential in the pharmaceutical industry to protecting the large investment it takes to bring a drug to market); Yusing Ko, *An Economic Analysis of Biotechnology Patent Protection*, 102 Yale L.J. 777, 800 (1992) (patents help biotech companies attract investment and thus increase innovation).[3]

Indeed, Myriad itself would not have invested the millions of dollars it took to develop and commercialize the *BRCA1* and *BRCA2* tests without the exclusivity provided by its patents:

> Myriad would not have made the investment of more than 200 million dollars in raising patient and physician awareness alone without the protection provided by the exact patents the Plaintiffs are challenging. . . . I am not aware of any diagnostic or pharmaceutical company that has made, or would be willing to make, this enormous investment without the benefit of a limited period of exclusivity engendered by patent rights.

Critchfield Declaration [D.N. 158] at ¶ 25 (emphasis in original).

B. Patents Spur Creativity and Competition

The latest invention almost never arises from whole cloth. Rather, invention stands on the shoulders of earlier invention. Even pioneering inventions like the light bulb, the telephone, and the airplane were based on earlier works. Patents foster this iterative process in at least three ways. First, the *quid pro quo* of the patent grant is that the inventor must disclose his or her invention, which he or she might otherwise keep secret for fear of misappropriation. Giles S. Rich, *The Relation between Patent Practices and the Anti-Monopoly Laws*, 24 J. Pat. Off. Soc'y

---

[3] The same is true in other young industries like software, which arose about the same time as the biotech industry. *See* Ronald J. Mann, *The Role of Patents in Venture-Backed Software Start-Ups*, Acad Advisory Council Bulletin (2007) at 1, 5, *available at* www.pff.org/issues-pubs/ip/bulletins/bulletin2.1softwareventurepatents.pdf (patents play a "role of considerable importance" for attracting investments in software-based start-up companies).

159, 177-180 (1942). Later scientists and inventors can thus build on the store of knowledge created by earlier patent disclosures. *Id.* at 180. Indeed, contrary to Plaintiffs' concern that patents inhibit the exchange of information, they actually facilitate full disclosure of inventions. Kieff, *Facilitating Scientific Research*, *supra* at 701 ("many biological scientists, perhaps most, regard the patent process as a means of institutionalizing secrecy, whereas it is in fact a time-tested way to assure broad and ready access to proprietary information") (citation omitted).

Second, patents make the exchange or acquisition of technological information--and thus the invention process itself--more efficient and less costly. *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J. L. & Econ. 265, 276-77 (1977). For example, upon review of another company's earlier patent, a competitor can avoid duplicating the patentee's effort and can allocate R&D resources to a different project. Alternatively, the competitor can avoid the mistakes of the first inventor. That is, most patents do not result in commercially viable products--the Patent Office awarded many patents for flying machines before the Wright brothers came along. Later innovators can learn from the failures of the earlier patentees without having to reinvent the proverbial wheel. Without a patent system, these failures would more likely remain unknown. *Id.* at 267-71. *See also* Giles S. Rich, *The Principles of Patentability*, 42 J. Pat. Off. Soc'y 75, 83 (1960) ("It should never be forgotten that *patented* inventions are published . . . *Patents* on inventions that have failed can promote progress") (italics in original).

Third, patents force would-be copyists and competitors to "design around," meaning to conceive of new solutions that do not infringe the patent. The threat of patent enforcement thus stimulates research and prompts competitors to develop new, perhaps superior products that might otherwise have gone undeveloped if the competitors could simply copy the earlier invention. *See Yarway Corp. v. Eur-Control USA, Inc.*, 775 F.2d 268, 277 (Fed. Cir. 1985)

("This court has indicated that the incentive to 'design around' patents is a positive result of the patent system"). The end result of this tension between patent owners and would-be copyists is that patents actually stimulate, rather than hinder, competition:

> industrial history discloses that [giant] corporations, at times and to some extent, have been prodded into undertaking such research and into developing improvements because of the threat of competition from occasional "outsiders," armed with patent monopolies, and supplied with funds by a few private enterprisers. Thus, paradoxically, monopoly may evoke competition: The threat from patent monopolies in the hands of such "outsiders" may create a sort of competition—a David versus Goliath competition—which reduces the inertia of some huge industrial aggregations that might otherwise be sluggish.

Picard v. United Aircraft Corp., 128 F.2d 632, 642-43 (2d Cir. 1942) (Frank, J., concurring); *see also* Blaxill & Eckardt, *The Invisible Edge*, *supra* at 57 (patents allow smaller companies to compete with larger or better funded companies).

C. Patents Prevent Free Riders and Encourage Wider Availability and Distribution of New Products

Inventors may or may not be motivated by economic gain. Some may invent for glory. Some out of academic curiosity. And some for altruistic reasons. The great insight of the patent system, however, is that even if a given inventor does not care about economic gain, the company that would commercialize the invention most certainly does. An individual inventor may not be an industrialist with the resources to manufacture or promote his or her invention. A patent, however, allows the inventor to put the invention into the hands of an entrepreneur or company that can. *Picard,* 128 F.2d at 642-43 ("But if we never needed, or do not now need, patents as bait for inventors, we may still need them, in some instances, as a lure to investors").

That process of getting an invention from the lab to the market often entails investment in further R&D to convert a raw invention into a commercially viable product, investment in regulatory compliance, sales and marketing, manufacturing ramp-up, and the like. All of these product development steps are just as much "innovation" as the initial conception or discovery.

Without patents, inventors may not risk disclosure for fear of misappropriation. Correspondingly, investors would not fund innovation absent the exclusive rights needed to prevent free-riding. In short, free riders (not patents) stifle innovation and the free-flow of information between inventors and producers. Patents promote these activities. *See* Erik S. Maurer, Note, *An Economic Justification for a Broad Interpretation of Patentable Subject Matter*, 95 Nw. U. L. Rev. 1057, 1060-63 (2001); Ko, *An Economic Analysis of Biotechnology Patent Protection*, *supra* at 799; Rich, *The Relation between Patent Practices and the Anti-Monopoly Laws*, *supra* at 177-180.

Many inventions will not make it into the hands of consumers at all absent strong patent protection. *See, e.g.,* Ko, *supra* at 799 ("A monopoly secured through patent protection could thus increase, rather than restrict, the use of an invention by facilitating its commercial introduction by innovating firms"). This principle is particularly true in the biotechnology industry, which requires such a large investment to commercialize a new product. *Id.* at 800.[4]

Judge Rich provided a good illustration of this concept. He recounts the plight of Mr. Spencer, who invented a new and improved wheelchair. Spencer neglected to patent his invention, however, preferring instead to donate his wheelchair to the world. The problem was that because the invention lacked patent protection, no company would risk manufacturing it because competitors could too easily copy it and thus reduce profits. As a result, the wheelchair never made it to market and could not benefit society. Giles S. Rich, *supra* at 179.

---

[4] One of Plaintiffs' complaints about Myriad's patents is that a few women have not been able to benefit from the *BRCA1* and *BRCA2* tests. That complaint ignores two important points. First, the alleged unavailability of the test has nothing to do with patents and everything to do with insurance coverage and healthcare policy. Second, over 400,000 patients have benefited from Myriad's tests. Without patent protection, Myriad would not have taken the steps necessary to commercialize them. Critchfield Declaration [D.N. 158] at ¶¶ 25, 29. In other words, nobody would benefit from the tests absent patent protection.

D. The U.S. Benefits From Patent Licenses

Another way that patents benefit the economy and public welfare is through licensing of patented technologies. Patent licensing has a number of benefits. For one, licensing facilitates a more productive division of labor between pure invention and commercialization. By licensing their inventions to others, inventors can focus on research without worrying about manufacturing, sales, and marketing. Second, in the realm of universities and research institutions, licensing can be used to fund additional research and the next wave of invention.

According to a 2004 survey, 137 educational and non-profit institutions had introduced to the market 567 new products under license agreements with commercial partners. *See* Assoc. of University Tech. Managers, *AUTM U.S. Licensing Survey: FY 2004: A Survey Summary of Technology Licensing (and Related) Performance for US. Academic and Nonprofit Institutions, and Technology Investment Firms* 2 (2005), *available at* http://www.autm.net/Surveys.htm. In the same year, licensing income totaled $1.385 billion spread out among 196 institutions. *Id.* at 3. Well-known institutions like Harvard University, the Dana-Farber Cancer Institute, and St. Jude Children's Research Hospital frequently obtain patents and license their discoveries to others. *Id.* at 31-32. Such institutions benefit from licensing by receiving royalties that help fund new research. In 2000 alone, universities realized over $1 billion from licensing their intellectual property. James Bessen & Michael J. Muerer, *Lessons for Patent Policy from Empirical Research on Patent Litigation,* 9 Lewis & Clark L. Rev. 1, 13 (2005).

In the life sciences field, patent licensing has led to enormous benefits for the American people. For example, Taxol, a potent cancer-fighting drug, was the result of a univ ersity researcher's discovery of a way to synthesize the active ingredient and make it more efficiently. The researcher licensed his invention to Bristol-Myers Squibb, which took the steps needed to

introduce the drug to market. *See* The Assoc. of University Tech. Managers, *Technology Transfer Stories: 25 Innovations That Changed the World*, 103-04 (2006), *available at* http://www.autm.net/documents/AUTM_BWR.pdf. Likewise, Exosurf, a synthetic lung surfactant used to treat respiratory ailments in premature infants, resulted from a discovery that a university researcher licensed to Burroughs-Wellcome (now GlaxoSmithKline), which brought the drug to market. *Id.* at 51—54. Without patents licensing, these drugs may never have reached the market and thus would not be available to save lives.

E. The Criticism of Gene-Related Patents Is Overstated

Plaintiffs have criticized Myriad, its licensing practices, and gene-related patents in general. In particular, Plaintiffs argue that such patents stifle research. But these criticisms are based on limited anecdotal evidence and ignore the big picture. Studies indicates that biotechnology patents "do not seem to have a substantial impact upon academic research . . . and only about 1% of the random sample of academics reported experiencing a delay or modification in their research due to patents." John P. Walsh *et al.*, *Patents, Material Transfers and Access to Research Inputs in Biomedical Research*, Final Report to the National Academy of Sciences' Committee on Intellectual Property Rights in Genomic and Protein-Related Inventions, 37 (2005), *available at* www2.druid.dk/conferences/viewpaper.php?id=776&cf=8. *See also* Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. Rev. 295, 299-300 (2007) ("the paucity of documented examples in which the fears surrounding gene patents have manifested themselves is striking . . . the case against gene patents is attenuated to the extent it relies on anecdotal evidence and unsubstantiated assumptions"). Indeed, as seen in the previous sections, patents actually stimulate and are used to fund research.

And while Plaintiffs contend that the government funds most basic research, in reality, private industry, buoyed by patents, contributes far more. *See* Kief, *Facilitating Scientific Research*, *supra* at 700-01 ("And by 1990, the single largest source of funding for research and development in [the biological sciences] field in the United States was private industry, not the federal government"); DiMasi, *The Price of Innovation*, *supra* at 157 (93.3% of new drugs approved in the U.S. during the 1990s were funded by private industry).

Myriad itself has paid millions of dollars in royalties to its research collaborators. Critchfield Declaration [D.N. 158] at ¶ 9. Myriad has underwritten or facilitated research by the National Cancer Institute and various universities. *Id.* at ¶¶ 4-9. Myriad's contributions are consistent with those of other patent owners. Plaintiffs ignore these contributions.[5]

F. Without Strong Patents, Innovation Will Decline

Without strong patent protection, new product development throughout the economy, but particularly in the life sciences field, will decline significantly. *See, e.g.*, Grabowski, *Patents, Innovation, supra* at 851 n.6 (highlighting a study showing that 60% of new pharmaceuticals would not have been developed without patent protection") and 853 ("Without a well-structured system of patent protection, neither the research pharmaceutical industry nor the generic industry would be able to grow and prosper, and the rate of new product introductions and patent expirations would decline significantly").

---

[5] Myriad should not be faulted for its licensing practices. A "patent owner is not in the position of a quasi-trustee for the public or under any obligation to see that the public acquires the free right to use the invention." *Hartford-Empire Co. v. United States*, 323 U.S. 386, 432 (1945)("A). Put another way, a patent owner is free to license a patent to others or to refuse to do so altogether. *See Dawson Chem. Co. v. Rohm and Haas Co.*, 448 U.S. 176, 215 (1980); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981); *Extratol Process, Ltd. v. Hiram Walker & Sons, Inc.*, 153 F.2d 264, 268 (7th Cir. 1946) ("The patentee is the sole judge of the licensee he shall select, to make, to sell, or to use his patented article. Patentee's reasons for selection of its licensee are of no concern to others").

The link between healthy patents and a healthy economy is strong. For example, the 1970s is generally seen as a decade of economic stagnation in which the U.S. lost its edge to foreign competition. Toyota and BMW began to compete with GM and Ford. Sony color TVs quickly outsold those of RCA and other American companies. Scholars explain that during that decade, antitrust enforcement was strong. As a result, many previously innovative companies, such as AT&T and IBM, were either forced under consent decrees to give away their intellectual property or, more often, voluntarily licensed their portfolios to competitors to avoid antitrust enforcement. Foreign companies often scooped up that intellectual property at bargain rates. Further, starting in the 1940s, academics began to doubt the value of patents and published their views extensively. Perhaps influenced by that academic philosophy and government policy, courts in the 1970s tended to invalidate patents more frequently and otherwise issued rulings that weakened patent protection. These policies, court rulings, and academic theories made patents less attractive to American businesses. As a result, patent applications by U.S. companies declined sharply during the 1970s. R&D spending and technological innovation followed suit and likewise declined. *See* Mark Blaxill & Ralph Eckardt, *The Invisible Edge, supra* at 66-69 and 232-238; David Silverstein, *Patents, Science and Innovation, supra* at 268-70 and 302-315.

Beginning in the 1980s, however, with some pro-patent rulings by the newly-established Court of Appeals for the Federal Circuit and a pro-patent shift in government policies and academic thinking, patents came back into fashion. An improved economy and a boom in technological innovation--including the blossoming of the biotechnology industry--soon followed. *Id.* Indeed, according to economic studies, biotechnology innovation and growth in the United States since 1980 is largely due to a revived patent system. Kieff, *Facilitating Scientific Research, supra* at 701 (citing studies by the National Research Council and others).

The decline of the American economy and hostility to patents in the 1970s mirrors today's situation. The last few years have seen a call for patent "reform" (a euphemism for weakening patents) and debate in Congress on the issue. Recent Supreme Court and Federal Circuit rulings have cut back on patent rights. In short, as in the 1970s, there been an attack on patents. Plaintiffs' case must be seen as part of this attack We are now mired in the deepest economic decline since the 1930s. Given the economic malaise, this country cannot afford to ignore the historical link between strong patents and a strong economy and must shape public policy and judicial philosophy accordingly.

G. Given the Benefits of Patents, the Scope of Patentable Subject Matter Should Be as Broad as Possible

As seen above, patents are a key factor in economic growth and prosperity. Vigorous enforcement of patents and policies that encourage patenting stimulate research and development, lead to new and improved technologies, and make such technologies more widely available to the public. Patents are particularly important to stimulating the introduction of new and improved treatments and diagnostics for cancer and other medical conditions. Given these important benefits, the scope of patentable subject matter should be extended as far as possible. *See* Mauer, A*n Economic Justification*, *supra* at 1087-1096; Holman, *The Impact of Human Gene Patents on Innovation and Access*, *supra* at 352 (". . . a patentability bar specifically targeting genes or DNA seems unwarranted at the current time").

As argued in Part II, Myriad's patents are directed to man-made compositions and methods, not to mere products of nature, and thus merit patent protection. The patented inventions make important new diagnostics and therapies available for saving lives. Upholding these patents is all the more important considering how much patents in general benefit the American people.

II. THE *BRCA1* AND *BRCA2* GENE-RELATED INVENTIONS ARE PATENTABLE UNDER 35 U. S. C. § 101

The essence of Plaintiffs' argument is that genes and their mutations occur in nature, products of nature are not patentable, and that Myriad's patents try to claim products of nature. But labeling the claimed DNA sequences and related products and methods as mere "products of nature" oversimplifies and, indeed, confuses the real inquiry:

> It only confuses the issue, however, to introduce such terms as "the work of nature" and the "laws of nature." For these are vague and malleable terms . . . . Everything that happens may be deemed "the work of nature," and any patentable composite exemplifies in its properties "the laws of nature.' Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.

Funk Bros. Seed Co. v. Kalo Inoculent Co., 333 U.S. 127, 134-35 (1948) (Frankfurter, J., concurring). The inquiry for establishing patent eligibility is not whether the claimed invention has a naturally-occurring analog or even whether the invention was extracted from nature. Rather, the court-approved inquiry--and the more thoughtful one--is whether the claimed invention (1) provides a new and useful function or application; (2) becomes newly available for use by virtue of its purification or its isolation from its natural environment; or (3) is transformative. The justification for this inquiry is easy and comports with the discussion on the value of patents in Part I above. That is, this inquiry focuses on whether the invention is new and useful and thus whether it benefits society.

The claims at issue in this case generally fall into two categories: isolated DNA claims and method claims (*e.g.*, diagnostic and cancer screening methods). Both categories provide new and useful functions, new and useful compositions not otherwise available for use, or new and useful transformations. The inventions thus benefit society and should be accorded proper respect and patent protection.

A. Eligibility for Patent Protection under Section 101 Is Broad

The first patent commissioner, Thomas Jefferson, believed that "ingenuity should receive a liberal encouragement." In keeping with this philosophy, the statute governing the scope of patent-eligible subject matter, 35 U.S.C. § 101, is worded broadly:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

35 U.S.C. § 101 (emphasis added). "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (upholding a patent on a genetically engineered microorganism). *See also Diamond* v. *Diehr*, 450 U.S. 175, 182 (1981) ("anything under the sun that is made by man" is patentable).

The only restriction to this principle is that "laws of nature," "natural phenomena," and "abstract ideas" are not patentable. *Id.* at 185. Contrary to Plaintiffs' argument, there is not a fourth category of exclusion under the rubric "natural products." Instead, isolated or purified products, even if they originated in nature before their isolation or purification, are patent-eligible under § 101. *See Parke-Davis & Co. v. H. .K. Mulford & Co.*, 189 F. 95 (S.D.N.Y. 1911) (L. Hand, J.) (purified adrenaline). Similarly, "naturally occurring" compounds that "do not exist in nature in pure form" are patentable. *In re Bergstrom*, 427 F.2d 1394, 1401 (C.C.P.A. 1970) (purified prostaglandins). As argued below, Myriad's isolated DNA inventions do not exist in nature and, in any event, provide new and useful applications not previously available.

Likewise, process claims involving laws of nature, natural phenomena, or abstract ideas are still patentable when the process represents a new and useful application of those laws, phenomena, or ideas. *Diehr,* 450 U. S. at 187; s*ee also Funk Bros. Seed Co.,* 333 U.S. at 130 ("He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it

which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end") (emphasis added). Myriad's method claims are patent-eligible because they are directed to new and useful ends.

B. Myriad's "Isolated" DNA Claims Are Patentable

Claims 1, 2 ,and 5-7 of the '282 patent, which Plaintiffs challenge, are directed to an "*isolated*" DNA coding for a BRCA1 polypeptide, "*isolated*" fragments thereof, and "*isolated*" mutants thereof. The term "isolated" is defined in the '282 patent's specification to mean that the particular sequence has been removed from its natural environment through the intervention of man-made tools or procedures:

> . . . substantially separated from other cellular components. . . . The term embraces a nucleic acid sequence or protein which has been removed from its naturally occurring environment, and includes recombinant or cloned DNA isolates and chemically synthesized analogs or analogs biologically synthesized by heterologous systems.

'282 patent, col. 19, *ll.* 8-19 (emphasis added). The term "isolated" appears in the disputed claims of the '492 and '473 patents and is given the same definition. S*ee* '492 patent, col. 17, *l.* 62, through col. 18, *l.* 5; '473 patent, col. 19, *ll.* 6-15.[6]

For at least a century, the patenting of compositions isolated from nature or purified beyond their natural state has been an established principle of U.S. patent law. For example,

---

[6] An essential first step in the assessment of a patent's scope is a proper construction of its claims, which is a matter of law for the Court. *Phillips v. AWH Corp.,* 415 F.3d 1303 (Fed. Cir. 2005) *(en banc).* Claim terms must be given their ordinary meaning from the perspective of a person of ordinary skill in the art at the time the application for patent was filed. *Id.* at 1313. The intrinsic evidence -- namely, the claim wording, the patent specification, and the prosecution history -- usually supplies the requisite meaning. *See, e.g., Gillette Co. v. Energizer Holdings, Inc.,* 405 F. 3d 1367, 1370 (Fed. Cir. 2005). If the patentee has defined the term in question (*i.e.*, in the specification or prosecution history), that definition is controlling. *Martek Biosciences Corp. v. Nutrinova, Inc.,* 579 F. 3d 1363, 1380, 1382 (Fed. Cir. 2009). Here, Myriad has clearly defined the term "isolated" in the specifications of its patents.

Louis Pasteur obtained a valid U.S. patent with claims directed to a "[y]east, free from organic germs of disease, as an article of manufacture." U.S. Patent No. 141,072 at Claim 2 (available from Google Patents at www.google.com/patents). In the early 1900s, Parke Davis & Co. obtained a patent for adrenaline, an otherwise naturally-occurring substance. In holding the patent to be valid, no less distinguished a jurist than Judge Learned Hand, then sitting in this Court, ruled that adrenaline purified from a gland was patentable. Judge Hand reasoned that purified adrenaline differed "not in degree, but in kind" from the adrenaline found in glands and that

> even if it were merely an extracted product without change, there is no rule that such products are not patentable. [The patentee] was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.

Parke-Davis & Co. v. H.K. Mulford & Co., 189 F. 95, 103 (S.D.N.Y. 1911) (emphasis added), *aff'd*, 196 F. 496 (2d Cir. 1912).

More recently, in a case involving prostaglandins (hormone-like chemicals that regulate various physiological functions, such as lowering blood pressure), the PTO rejected claims for certain isolated prostaglandins on the theory they were mere "naturally occurring" secretions. On appeal, the court reversed, observing that the isolated forms were not naturally occurring:

> At the outset we would observe that what appellants claim--pure PGE(2) and pure PGE(3)--is not "naturally occurring." Those compounds, as far as the record establishes, do not exist in nature in pure form, and appellants have neither merely discovered, nor claimed sufficiently broadly to encompass, what has previously existed in fact in nature's storehouse, albeit unknown, or what has previously been known to exist.

In re Bergstrom, 427 F.2d 1394, 1401 (CCPA 1970). As noted above, Claims 1, 2 and 5-7 of the '282 patent are directed to an "*isolated*" DNA coding for a BRCA1 polypeptide, "*isolated*" fragments thereof and "*isolated*" mutants thereof.

Similar to the purified adrenaline and prostaglandins discussed above, nucleic acid (*i.e.*, DNA) molecules that have been isolated from their natural environment (such as the molecules claimed in Myriad's '282, '492, and '473 patents) have become for every practical purpose new things, new compositions that are different from what existed in nature. By virtue of their isolation, these molecules have been transformed into new and useful compositions with practical applications previously unavailable to humankind.

More specifically, the claimed nucleic acid molecules were substantially separated (*i.e.*, "isolated," as the term is defined in the patents) from other cellular components. Accordingly, these nucleic acid molecules differ from the naturally occurring genes at least in the degree of their purification. More important, they also differ in kind. As isolated nucleic acid molecules, they have new properties and characteristics that allow them to perform new technological functions that could not have been performed or achieved using the naturally occurring genes.

For example, unlike their naturally-occurring brethren, isolated nucleic acid molecules can be used in genetic tests to determine the presence or absence of a specific DNA sequence that may be associated with a predisposition to a particular disease or responsiveness to a particular drug or therapy. *See* James D. Watson *et al.*, *Recombinant DNA* 539 (2d ed. 1992).[7] These isolated nucleic acid molecules may also be used to make DNA vaccines or to genetically engineer cells that can be grown in large scale cell cultures to, for example, produce large quantities of a therapeutic antibody or other proteins. *Id.* at 460. Isolated nucleic acid molecules may also be used to produce new agricultural products with improved properties like pest and disease resistance. *Id.* at 471-75. Thus, in the case of isolated nucleic acid molecules, human

[7] Naturally occurring genes cannot be used in diagnostic applications because, among other things, they (a) are too big to be able to practically hybridize to a patient's DNA and (b) are not labeled and, thus, cannot be detected.

intervention has done much more than just removing a natural product from its environment and purifying it. In these cases, scientists have produced a product with functions, properties, and characteristics that are different in kind from those of the naturally occurring molecule.

A brief review of the most basic procedures in the complex science of recombinant DNA technology further documents the difference between the isolated DNA molecules claimed in Myriad's patents and naturally occurring DNA. For example, the claimed isolated DNA molecules (*e.g.*, the *BRCA1* nucleic acid molecule of SEQ ID NO:1 of the '282 patent and the *BRCA2* nucleic acid molecule of SEQ ID NO:1 of the '492 patent) are cDNA molecules. A cDNA molecule is a single-stranded DNA molecule "complementary" to a corresponding RNA molecule. *See* Benjamin Lewin, *Genes V* 164 (1994). cDNA is synthesized from an RNA template by reverse transcriptase, an enzyme that is not naturally present in a human cell and not encoded by a human gene but rather encoded by reverse-transcribing viruses. *Id.* at 164, 1237. cDNAs are either made by retroviruses or are synthetic molecules made from mRNA by enzymatic reactions carried out in the laboratory. Watson *et al.*, *Recombinant DNA, supra* at 102-104. Thus, cDNAs such as *BRCA1* and *BRCA2* are not synthesized *in vivo* during regular cellular DNA replication or transcription of genes but rather can only be produced in the lab. *See* Lewin, *Genes V*, *supra* at 1237. [8]

By definition, cDNA molecules are also different from naturally-occurring genes. Naturally occurring genes are composed of "exons" and "introns," which are defined in Plaintiffs' and in Myriad's summary judgment papers. Unlike naturally-occurring genes, cDNA

---

[8] While mRNAs result from regular cellular gene expression *in vivo*, they are chemically distinct from cDNAs. They contain different sugars and otherwise differ in composition. *See* Watson *et al.*, *Recombinant DNA, supra* at 14, 37-38. The sugar present in DNA is deoxyribose, while the sugar present in RNA is ribose. *Id.* at 14. As such, they are different chemical moieties with different properties and functions.

molecules contain no introns. *See* Lewin, *Genes V, supra* at 150 and Figure 6.18 (showing that introns are removed from precursor RNA when exons are spliced together). Thus, cDNA molecules (such as the ones claimed in the '282 patent and the '492 patent) are very different from genes that naturally exist in a cell.[9]

Contrary to Plaintiffs' arguments that cases like *Parke-Davis* are distinguishable, they are right on point and support patentability of the gene-related inventions in this case. The point of *Parke-Davis* and similar cases is not, as Plaintiffs argue, that the isolated or purified matter had a different function from the naturally-occurring version. Indeed, as taught by the underlying patent in *Parke-Davis*, purified adrenaline has the same biological function as adrenaline produced in the body--namely "hemostatic, blood-pressure-raising, and astringent properties." *See* U.S. Pat. No. 730,176 (available at www.google.com/patents). Rather, the point is that isolation or purification "renders available for use the above-mentioned properties of the suprarenal glands in a stable, pure, and concentrated form." *Id.* at col. 1, *ll.* 44-50. In the same way, the claimed nucleic acid molecules in this case have, by virtue of their isolation, been rendered available for use. Neither naturally occurring genes nor the proteins they create in the cells of the body are available for use.

In any event, isolated nucleic acid molecules provide and enable various entirely new technological functions that are different from the functions of the naturally occurring genes present in the body. For example, as seen above, isolated nucleic acid molecules may be used to

---

[9] Contrary to Plaintiff's arguments, there is no process or mechanism within the human body that would allow the isolation of nucleic acid molecules. As basic procedures in recombinant DNA demonstrate, identifying, isolating, and purifying genes can be accomplished only through a series of complicated steps requiring human intervention. *See* Watson *et al.*, *Recombinant DNA* , *supra* at 99-133. Indeed, the majority of the claimed nucleic acid molecules do not even exist in nature in the form in which they are claimed in the Myriad patents. For example, the DNA fragments and cDNA molecules claimed in the '282 patent do not exist naturally in the human body. Rather, they are "man made" compositions.

diagnose diseases, which function the naturally occurring genes cannot perform. Isolated nucleic acid molecules may also be used to make DNA vaccines or to produce large quantities of a therapeutic antibody--again, functions that the naturally occurring genes cannot perform.

In short, the isolated DNA molecules of Myriad's patents have been isolated from the human cell context in which naturally occurring genes are found, and are different in kind from such genes in their form, structure, and chemical composition. They enable new and valuable applications previously unknown and unavailable to man.

C. Myriad's Claimed Methods Are Patentable

Even though laws of nature, natural phenomena, and abstract ideas may not be patentable, it is well-established that "'an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.'" *In re Bilski,* 545 F.3d 943, 953 (Fed. Cir. 2008) (*en banc*) (quoting *Diehr*, 450 U.S. at 187), *cert. granted*, 129 S. Ct. 2735 (2009). "A claimed process is patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." *Id.* In keeping with this formula, the Federal Circuit held that a method for calibrating dosage of thiopurine drugs by measuring metabolites in subjects having gastrointestinal disorders is patent-eligible because determining levels of the metabolite in the subject "necessarily involves a transformation, for those levels cannot be determined by mere inspection." *Prometheus Labs. v. Mayo Collaborative Servs.,* 581 F.3d 1336, 1347 (Fed. Cir. 2009). Further, the step of determining levels of the metabolite involves a transformation of the blood sample, *e.g.*, by means of "[s]ome form of manipulation, such as high pressure liquid chromatography." *Id.*

Myriad's diagnostic method claims--such as those found in the '999, '001, '441, and '857 patents--satisfy § 101 because each requires the transformation of a sample, *e.g.*, a tissue or

blood sample, in order to isolate the patient's DNA and analyze it. Indeed, because the *BRCA1* and *BRCA2* sequences were unknown prior to Myriad's invention, the method claims here present a stronger case for patentability than in *Prometheus*. There the metabolites were known and transformation was needed only to make it possible to measure and compare metabolite levels with dosage requirements. But in Myriad's case, transformation is required to isolate the DNA sequence from the patient's tissue sample in order to compare it to previously unknown *BRCA* sequences and to possible mutation patterns. Further, these claims involve the practical application of newly discovered gene sequences for a new and useful end: the diagnosis of a subject as being predisposed to a particular disease (*e.g.*, breast cancer) or the treatment of a subject by determining whether the subject will respond to a particular therapy.

Breast cancer is one of the most significant diseases affecting women. Worldwide, breast cancer is the second most common type of cancer after lung cancer and the fifth most common cause of cancer death. *See* World Health Organization, *Fact Sheet No. 297: Cancer* (2006), *available at* http://www.who.int/mediacentre/factsheets/fs297/en/index.html. Treatment of breast cancer at a later stage of the disease is often futile and disfiguring, making early detection a high priority in the medical management of the disease. Myriad's diagnostic process claims are based on the discovery of a previously unknown relationship between the *BRCA1* and *2* genes and a predisposition to breast cancer. A diagnostic process applying this relationship can make the difference between life and death for thousands of people. As such, these diagnostic processes represent extremely useful inventions deserving patent protection.

Diagnostic process claims, such as claim 2 of the '857 patent, as a whole require significant human intervention. Detecting a difference between the germline sequence of the *BRCA2* gene in a tissue sample from a subject with the germline sequence of the wild-type

BRCA2 gene requires testing of a sample that has been derived from the subject. Testing the sample entails transforming the sample such that detection of the gene alteration can be made possible. For example, the sample can be contacted with a labeled probe that is able to hybridize to the germline sequence within the sample and detect it. *See* Lewin, *Genes V*, *supra* at 645-47. Methods for extracting and detecting the DNA or RNA sequences are quite intensive and complex. *See, e.g.,* Watson *et al.*, *Recombinant DNA*, *supra* at 129-130.

Thus diagnostic claims relating to personalized medicine, such as the method claims of the Myriad patents, constitute not phenomena of nature, but instead elegant and simple, yet novel and extremely useful innovations that employ extensive human intervention to produce useful results. Thus, claims directed to such methods are patentable under 35 U.S.C. §101 and established principles of U.S. patent law.

III. THE PATENT GRANTS HERE ARE CONSTITUTIONAL

An individual patent grant by the USPTO cannot violate the Constitution. The so-called "IP Clause," U.S. Const., art. I, § 8, cl. 8, merely authorizes Congress to secure for authors and inventors exclusive rights to their writings and discoveries but otherwise places no limits on how broad or narrow eligible subject matter should be. Instead, the Constitution leaves it to Congress to "make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers." Art. I, § 8, cl. 18. Congress has done so in 35 U.S.C. § 101, discussed above. Congress's decision in § 101, to permit patents on "any" new and useful compositions of matter and on processes, if challenged, must be upheld on a rational basis test. *See Eldred v. Ashcroft,* 537 U. S. 186, 199-208 (2003). As demonstrated in Part I above, patents promote innovation and benefit society. As seen in Part II, Myriad's patents benefit society in spades. Plaintiffs'

offer no substantive evidence to contradict the well-established rational relationship between the patent system and furtherance of the Constitution's stated objectives.

Plaintiffs" First Amendment attack fares no better. Although presented as an attack on particular patents, Plaintiffs' challenge is to the patent system itself. The First Amendment, however, does not impose any substantive limitation on Congress's power to enact patent laws, much less on the authority of the USPTO to issue particular patents. In addition, the patent laws have already been interpreted to accommodate any First Amendment concerns. *See. e.g., Kewanee Oil Co. v. Bicron Corp.,* 416 U. S. 470, 480 - 81 (1974) (rather than restricting speech, patent law encourages disclosure, thus stimulating ideas and innovation). Finally, Plaintiffs' reductive misinterpretation of the claims under attack as comprising mere information, instead of chemical compositions and methods of using them, dooms their First Amendment claim.

CONCLUSION

For the foregoing reasons, the Boston Patent Law Association respectfully urges this Court to uphold the vigor of the patent system and all of the benefits it provides by (a) rejecting Plaintiffs' claims, (b) granting summary judgment for Myriad, and (c) granting the USPTO's motion for judgment on the pleadings.

Dated: January 13, 2010

By: /s/Lee Carl Bromberg
Lee Carl Bromberg
Lori J. Shyavitz
Attorneys for *Amicus Curiae*
Boston Patent Law Association
265 Franklin Street
Boston, MA 02116
(617) 449-6500
lbromberg@mccarter.com
lshyavitz@mccarter.com

Of Counsel:
Erik Paul Belt
Co-Chair, BPLA *Amicus* Committee
Maria Laccotripe Zacharakis, Ph.D.
McCarter & English, LLP
265 Franklin Street
Boston, MA 02116
(617) 449-6500
ebelt@mccarter.com
mzacharakis@mccarter.com

CERTIFICATE OF SERVICE

This is to certify that on January 13, 2010, a true and correct copy of the foregoing Boston Patent Law Association's Amicus Brief Supporting the Myriad Defendants' Opposition to Summary Judgment, Their Cross-Motion for Summary Judgment, and the USPTO's Motion for Judgment on the Pleadings has been served on registered counsel of record via the Court's ECF system.

Dated: January 13, 2010

/s/Lori J. Shyavitz
Lori J. Shyavitz